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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/868,442	MITRAGOTRI ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,74-110,112 and 114-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *77-79,89,93 and 100* is/are allowed.

6)☒ Claim(s) *72,74-76,80-88,90-92,94-99,101,103-110,112 and 114-119* is/are rejected.

7)☒ Claim(s) *102* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 72, 74 – 76, 82, 83, 90, 97, 101, 107, 112 and 114 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,009,343 to Shain et al.

In reference to claims 72, 74 – 76, 82, 83, 90, 97 and 101, Shain et al. discloses applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 2, lines 64 - 67); extracting at least one analyte from the area of skin (Col. 4, line 49); receiving the analyte in a sensing zone (18) in communication with the area; and continuously determining the quantity of the analyte in the sensing zone (Col. 3, lines 14 – 24). Shain et al. discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum (Col. 3, lines 33 – 35), electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. The ultrasound is applied to create a result selected from pumping body fluid and fluid components, activating gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase temperature and set up standing waves (Col. 3, lines 60 - 64). Collecting the at least one analyte comprises using a method from the group of absorption, adsorption, phase

separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof (Col. 3, lines 50 – 53). The mechanical collection method comprises applying vacuum, pressure or acoustic forces. The determining step includes a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 3, lines 17 - 20).

In regards to claims 107, 112 and 114, Shain et al. discloses applicant's claimed invention including a low frequency ultrasonic transducer (Col. 2, lines 64 - 67); means providing an extraction transport force (14); a sensing zone (18); and a sensing device in the sensing zone for continuously measuring the quantity of at least one analyte (Col. 3, lines 14 – 24). Shain et al. discloses means providing an extraction transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof (Col. 2, line 67 – Col. 3, line 2). The sensing device senses the presence of at least one analyte by applying a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 3, lines 17 –24).

3. Claims 72, 74 – 76, 80 - 86, 88, 90 - 92, 97, 98, 101, 107, 108, 112, 114 and 117 – 119 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2002/0045850 to Rowe et al.

In reference to claims 72, 74 – 76, 80- 86, 88, 90 - 92, 97, 98 and 101, Rowe et al. discloses applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound [0072]; extracting at least one analyte from the area of skin (Col. 4, line 49); receiving the analyte in a sensing zone in communication with the area [0092]; and continuously

determining the quantity of the analyte in the sensing zone [0093]. Rowe et al. discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof [0085]. The ultrasound is applied to create a result selected from pumping body fluid and fluid components, activating gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase temperature and set up standing waves [0085].Rowe et al. discloses a plurality of ultrasound-producing devices [0044] having at least one different operating characteristic selected from frequency, intensity, and coupling media [0085]. Collecting the at least one analyte comprises using a method from the group of absorption, adsorption, phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof [0085]. The determining step includes a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof [0093].

In regards to claims 107, 108, 112 and 114, Rowe et al. discloses applicant's claimed invention including a low frequency ultrasonic transducer[0072]; means providing an extraction transport force [0085]; a sensing zone [0093]; and a sensing device in the sensing zone for continuously measuring the quantity of at least one analyte [0093]. Rowe et al. discloses means providing an extraction transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof[0085]. The sensing device senses the presence of at least one analyte by applying a sensing

method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof [0093].

In regards to claims 117 – 119, Rowe et al. discloses a system and method for blood glucose determination including a low frequency ultrasound transducer for increasing the permeability of the skin [0092]; an extraction device for extracting glucose from the skin [0085]; a receiving device for receiving the glucose; a gel in the receiving device; at least one glucose sensitive reagent that changes a characteristic of the gel; and a monitoring device for continuously monitoring the change in the characteristic [0093].

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. as applied to claim 74 above, and further in view of U.S. Patent No. 6,468,229 to Grace et al.

In reference to claims 86 and 87, Shain et al. discloses using a mechanical force to enhance the physical movement of liquid across the skin (Col. 3, lines 50 – 53), but fails to disclose using a tensioner having a cavity to collect the fluid therein. Grace et al. discloses a tensioner (Figures 2A – G) having a cavity (26) for the collection of fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. to include the steps of using a tensioner having a cavity to collect fluid therein as taught

by Grace et al. in order to increase the amounts of interstitial fluids that are collected (Col. 2, lines 25 – 30).

6. Claims 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. as applied to claim 90 above, and further in view of U.S. Patent No. 6,503,198 to Aronowitz et al.

In reference to claims 95 and 96, Shain et al. fails to disclose a hydrophobic coating being applied to the skin prior to extracting a body fluid from the skin. Aronowitz et al. teaches applying a hydrophobic coating to the skin prior to fluid extraction from the skin (Col. 16, lines 16 – 46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. to include the step of applying a hydrophobic coating to the skin prior to fluid extraction as taught by Aronowitz et al. in order to enhance the permeation of the skin (Col. 16, lines 38 – 44).

7. Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. in view of WO 97/30749 to Abbott Laboratories.

In regards to claim 99, Shain et al. increasing a permeability level of an area of skin with low frequency ultrasound (Col. 2, lines 64 - 67); extracting at least one analyte from the area of skin (Col. 4, line 49); receiving the analyte in a sensing zone (18) in communication with the area; and continuously determining the quantity of the analyte in the sensing zone (Col. 3, lines 14 – 24). However, Shain et al. fails to disclose including a chemical method comprising applying a hydrophilic gel to receive the at least one analyte. Abbott Laboratories discloses a method for analysis of at least one analyte in the body utilizing ultrasound and including a chemical method comprising applying a hydrophilic gel to receive the at least one analyte (Page 9, lines 20 – 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the method as disclosed by Shain et al. to include a chemical method comprising applying a hydrophilic gel to receive the at least one analyte as taught by Abbott Laboratories in order to aid in the transporting of the at least one analyte to the sensing zone (Page 9, lines 20 – 30)

8. Claims 103 – 106, 109, 110, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. as applied to claims 72 and 107 above, and further in view of U.S. Patent No. 5,722,397 to Eppstein.

In regards to claims 103 – 106, 109, 110, 115 and 116, Shain et al. fails to disclose providing an output controlled by a microcontroller for a user interface having an alarm that indicates an abnormal analyte concentration and trend information that is downloadable. However, Eppstein discloses a method for analysis of at least one analyte in body fluid including providing an output for a user interface having an alarm that indicates an abnormal analyte concentration (Col. 21, lines 10 – 18) and trend information that is downloadable (Col. 19, lines 7 – 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. to provide an output as taught by Eppstein in order to indicate to the user or diagnostician the need for administration of appropriate medication if necessary (Col. 21, lines 10 – 13).

Allowable Subject Matter

9. Claim 102 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 77 – 79, 89, 93 and 100 are allowed.

Response to Arguments

11. Applicant's arguments filed 12/21/05 have been fully considered but they are not persuasive. Applicant has asserted that neither Shain et al. nor Rowe et al. disclose continuously determining the quantity of at least one analyte of the body fluid in the sensing zone. The Examiner disagrees. Applicant is not arguing that Shain et al. or Rowe et al. fail to disclose determining the quantity of an analyte, but that the determining is not performed continuously. However, continuously is taken by the Examiner to be "marked by uninterrupted extension in space, time, or sequence" (Merriam-Webster's Collegiate Dictionary, 10th ed.). In this regard, both Shain et al. and Rowe et al. disclose continuously determining the quantity of at least one analyte in that the measurement is continuous over the time period taken to perform the measurement. Applicant submits that such an interpretation is unreasonably broad. However, office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible,

during the administrative process."). During examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, **>367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004)< (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. Because Applicant has failed to provide any clear definition in the specification, "continuously" is taken by the Examiner to be "marked by uninterrupted extension in space, time, or sequence" (Merriam-Webster's Collegiate Dictionary, 10th ed.). The claims contain no indication as of the period of time that the analyte is to be monitored. The Examiner maintains that the broadest reasonable interpretation of "continuously determining the quantity" is anticipated by Shain et al. and Rowe et al. for continuously determining the quantity of at least one analyte in that the measurement is continuous over the time period taken to perform the measurement.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,805,623 to Jöbsis teaches a sensor for monitoring an analyte in a body fluid which can monitor continuously or over discreet time periods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

MAX F. HINDENBURG
PATENT EXAMINER